



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

MAR 5 2007

Food and Drug Administration
Rockville MD 20857

Re: Ionsys (Patent # 5,697,896)
Ionsys (Patent # 6,425,892)
Docket Nos.: 2007E-0012
2007E-0013

The Honorable Jon Dudas
Under Secretary of Commerce for Intellectual Property and
Director of the United States Patent and Trademark Office
Box Patent Extension
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Director Dudas:

This is in regard to the application for patent term extension for U.S. Patent Nos. 5,697,896 and 6,425,892 filed by Alza Corporation under 35 U.S.C. § 156. The human drug product claimed by the patents is Ionsys (fentanyl hydrochloride), which was assigned NDA No. 21-338.

A review of the Food and Drug Administration's official records indicates that this product was subject to a regulatory review period before its commercial marketing or use, as required under 35 U.S.C. § 156(a)(4). However, our records also indicate that Ionsys does not represent the first permitted commercial marketing or use of the product, as defined under 35 U.S.C. § 156(f)(1), and interpreted by the courts in *Glaxo Operations UK Ltd. v. Quigg*, 706 F. Supp. 1224 (E.D. Va. 1989), *aff'd*, 894 F. 2d 392 (Fed. Cir. 1990). The active ingredient in Ionsys, fentanyl hydrochloride, is a salt of an active ingredient that has been previously approved for commercial marketing or use, in Duragesic-100, NDA 19-813, fentanyl.

The NDA was approved on May 22, 2006, which makes the submission of the patent term extension applications on July 19, 2006, timely within the meaning of 35 U.S.C. § 156(d)(1).

Should you conclude that the subject patents are eligible for patent term extension, please advise us accordingly. As required by 35 U.S.C. § 156(d)(2)(A) we will then determine the applicable regulatory review period, publish the determination in the *Federal Register*, and notify you of our determination.

Please let me know if we can be of further assistance.

Sincerely yours,

Jane A. Axelrad
Associate Director for Policy
Center for Drug Evaluation and Research

Dudas - Ionsys (6,425,892)

Patent No. 6,425,892

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